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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,174	07/10/2001	Inga Laursen	0459-0636P	8992

2292 7590 08/26/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

902,174

Applicant(s)

LAURSEN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 5/28/03
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-8, 10-19 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-8, 10-19 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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Amendment of 5/28/03 has been entered. Claims 1-8 and 10-19 are pending and under examination.

Claims 1, 13, 15, 18 and 19 are objected to because of the following informalities: In step (e) of claims 1, 18 and 19, "re move" should be ~~remove~~. In step (k ) of claims 13 and 15, it is believed that "(k )" should be ~~(j)~~—(compare to recitations in claims 1, 18 and 19).

Appropriate correction is required.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, step (i) "to an anion exchange" is incomplete.

In steps (j) and (K) "the cation exchange resin of step (j)" lacks antecedent basis.

Claims 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13 and 15 contain new matter in step (K) by virtue of referring to previous step (j), Instead of (j), as in original claim 1.

Should this change alter the meaning or scope of the claim, applicant has improperly changed the nature of the claimed invention.

Claim 15 contains new matter in step (i) by virtue of not requiring application to both an anion exchange resin and a cation exchange resin, as in original claim 1.

Claims 1-2, 11-12, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by applicant's admitted state of the art regarding the octagons liquid formation and/or any of Mollnes et al., Brenner or Biesert for reasons of record in Paper 3.

Applicant has urged that the instantly claimed product is distinguished from the prior art by virtue of the lower IgA content of the former – e.g. as shown in the of the Table at specification page 26. This is unconvincing because the claim per se has no requirement that the IgA content be below a certain level. It is noted that specification page 21 merely states that “the IgG product should contain less than 6 mg of IgA/L”; there is no requirement, even in the specification, that the IgA level be below this value.

Additionally it is to be noted that the preparation of applicant (IVIG, SSI in Table) was obtained with the use of a particular precipitant and particular anion and cation exchange resins; it was obtained with the use of particular washing and eluting conditions. The claims are not limited to these particularly exemplified parameters of purification. Since not all precipitants, resins, washing agent and eluting agents need be equally effective in separating IgG from IgA, there is no requirement that the claimed product have a low IgA content, as shown in the Table of page 26. Applicant's urgings are not commensurate with claim scope.

Claims 1-2, 11-12, 15 and 17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Applicant's admissions at the previously noted portions of the disclosure in the above 102(b) rejection are taken as evidence that applicant is not the inventor.

Since applicant has not overcome the 102(b) rejection stated above, the 102(f) rejection is also maintained.

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Claims 1-8, 10 and 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Doleschel et al. (4,880,913), for reasons of record.

Applicant has urged various differences exist. The examiner will address each in turn.

Regarding PEG content, applicant has urged this is higher in Doleschel et al's. Product. PEG content is not a limitation of any instant claim. Further, the teachings of Doleschel et al. of removing PEG by ultra or diafiltration against a 5x amount of buffer (Ex. 2) are merely exemplary; claim 1 of Doleschel et al. has no limitations regarding the particular volume of buffer used for ultra or diafiltration.

With respect to applicant's urgings that Doleched et als' product cannot be obtained by a manufacturing process, it is noted that economic considerations are not relevant. In re Farrenkopf 219 ISPQ 1983. Urgings regarding product safety for i.v. administering are unconvincing; see claim 1 of Doleschel et al.

Regarding IgA content, applicant's urgings concerning the sensivity of Doleschel et al's assay for IgA content are mere attorney pleadings not backed by comparative evidence in declaration form. Also, as noted supra regarding the Octagon product, claims 1, 15, 17 and 19 have no limitations regarding the IgA content.

Regarding the distribution of IgG subclasses, applicant has urged that the preparation of Doleschel et al. does not fall within the range recited in instant claim 6. This argument is based on a comparison of applicant's product to others, which do not include that of Doleschel et al. (Table at page 26) and is thus not germane to the rejection. Further, even if the examiner were to withdraw rejection of claim 6, Doleschel et al. teach sufficiently to show the aspect recited

instant claim 3, part d); see Doleschel et al. at col. 2, line 5. All other independent claims recited nothing regarding IgG subclass distribution.

Applicant has also urged that the ion exchange processes of Doleschel et al. and applicant differ and thus yield different products. As noted supra regarding the rejection based upon the Octagon product, the examiner considers instant claims 1, 15 and 18-19 as encompassing the use of numerous precipitants, anion and cation exchange resins, washing agents, etc. claims thus encompass products having features other than those exemplified in the Table at page 26.

Applicant has urged that Doleschel et al. do not include steps for virus reduction and that their product is thus unsafe. The examiner notes that the heating treatment disclosed at col. 3 lines 30-36 is a conventional treatment for inactivating viruses. It is noted applicant considers the term "virus inactivating agent" as encompassing an agent or virus agent or method; thus the term encompasses heating. See specification page 15.

Applicant has urged that Doleschel et al. do not teach a pH value or stability of a liquid product and that their product may be unsafe for i.v. administration. It is noted that no instant claim recites any quantitative limitations regarding stability and that Doleschel et al. teach that their liquid product is stable upon prolonged storage (col. 4, lines 17-20). Also, claim 1 of Doleschel et al. recites, "is stable in liquid form and can be administered intravenously" and must be presumed valid. As to pH, the pH of the preparation of Doleschel et al., note col. 3, line 51 – col. 4, lines 20.

Claims 1-2, 15, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Mamidi et al. (6,162,904) for reasons of record.

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Applicant has urged that the product of Mamidi et al. differs from that instantly by virtue of having exemplified IgA contents of 22 and 78 mg/L, which are in consistent with claim 3. For this reason the examiner has withdrawn the rejection of claim 3 and its dependents. However, as noted supra regarding the Octagam product, claims 1 and 15 recite no limitations regarding IgA content.

The examiner concurs that new claim 18 should not be rejected over Mamidi et al. However, claim 19 is included because both examples of Mamidi et al. show aggregate contents of 0.3% or less.

Claims 1 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doleschel et al. or Mamidi et al., alone or in view of applicant's admissions.

The rejection of record is maintained since applicant's urgings have not overcome the rejection of product claim 1. Applicant's urgings regarding the lack of stabilizers in the instant product are not relevant to either the instant product or method claim(s), because there is no negating limitation regarding the use of stabilizers and because the open nature of the claims would permit addition of a stabilizer. Applicant is arguing an advantage, which is not related to any limitation in the claims.

Applicant's urgings filed on 5/28/03 have been considered but are unconvincing.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday - Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. A. Saunders:jmr  
August 20, 2003

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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